**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

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| AMGEN INC. and AMGEN MANUFACTURING LIMITED,<br><br>Plaintiffs,<br><br>v.<br><br>MYLAN INC., MYLAN PHARMACEUTICALS INC., MYLAN GMBH and MYLAN N.V.,<br><br>Defendants. | Civil Action No. 17-cv-01235-MRH<br><br>***Electronically Filed***<br><br>**JURY TRIAL DEMANDED** |

**DEFENDANTS MYLAN INC.'S, MYLAN PHARMACEUTICALS INC.'S, MYLAN GMBH'S AND MYLAN N.V.'S ANSWER, DEFENSES AND COUNTERCLAIMS**

Defendants Mylan Inc., Mylan Pharmaceuticals Inc. ("MPI"), Mylan GmbH and Mylan N.V. (collectively, "Defendants" or "Mylan"), hereby answer the Complaint of Amgen Inc. and Amgen Manufacturing Limited (collectively, "Plaintiffs" or "Amgen"), for which every allegation not expressly admitted is denied, as follows:

**THE PARTIES**

1. Amgen Inc. ("Amgen") is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. Founded in 1980, Amgen is a pioneer in the development of biological human therapeutics. Today, Amgen is the largest biotechnology company in the world, fueled in part by the success of NEULASTA® (pegfilgrastim).

**ANSWER:** Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the U.S. Food and Drug Administration's ("FDA") electronic records identify Amgen Inc. in connection with Biologic License Application ("BLA") No. 125031 for NEULASTA® (Pegfilgrastim) Injection. Defendants are without

knowledge and information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 1, and therefore deny the same.

2. Amgen Manufacturing Limited ("AML") is a corporation existing under the laws of the Territory of Bermuda with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777. AML manufactures and sells biologic medicines for treating particular diseases in humans. AML is a wholly owned subsidiary of Amgen.

**ANSWER:** Paragraph 2 contains legal conclusions to which no answer is required. Defendants are without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 2, and therefore deny the same.

3. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business in Canonsburg, Pennsylvania at 1000 Mylan Boulevard Canonsburg, Pennsylvania 15317. Upon information and belief, acting in concert with the other Defendants, Mylan Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

**ANSWER:** Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan Inc. is a Pennsylvania corporation having a place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Defendants deny that Mylan Inc. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 3.

4. Upon information and belief, Mylan Inc. is a United States agent for Mylan GmbH and Mylan N.V. for purposes including, but not limited to, corresponding with the Food and Drug Administration ("FDA").

**ANSWER:** Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

5. Upon information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, with its principal place of business in Morgantown, West Virginia at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, acting in concert with the other Defendants, Mylan Pharmaceuticals Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

**ANSWER:** Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that MPI is a West Virginia corporation having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Defendants deny that MPI is a proper party to this action. Defendants deny all remaining allegations of Paragraph 5.

6. Upon information and belief, Mylan Pharmaceuticals Inc. is a United States agent for Mylan GmbH and Mylan N.V. for purposes including, but not limited to, corresponding with FDA.

**ANSWER:** Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH submitted BLA No. 761075 to FDA ("Mylan GmbH's BLA"), pursuant to 42 U.S.C. § 262(k), which identifies MPI as a U.S. contact with respect to Mylan GmbH's BLA. Defendants deny all remaining allegations of Paragraph 6.

7. Upon information and belief, Mylan GmbH is a corporation existing under the laws of the Republic of Switzerland with its principal place of business at Thurgauerstrasse 40 Zurich, 8050 Switzerland. Upon information and belief, acting in concert with each of the other Defendants, Mylan GmbH is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

**ANSWER:** Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH is a Swiss corporation having a place of business at Thurgauerstrasse 40, 8050 Zürich, Switzerland. Defendants deny all remaining allegations of Paragraph 7.

8. Upon information and belief, Mylan N.V. is a corporation existing under the laws of the Republic of Netherlands with its global headquarters and principal offices located in Canonsburg, Pennsylvania, and its principal executive offices located Hatfield, Hertfordshire, England. Upon information and belief, acting in concert with each of the other Defendants, Mylan N.V. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

**ANSWER:** Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan N.V. is a corporation existing under the laws of the Netherlands with a place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Defendants further admit that Mylan N.V. has offices in Canonsburg, Pennsylvania. Defendants deny that Mylan N.V. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 8.

9. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan GmbH are wholly owned subsidiaries of Mylan N.V.

**ANSWER:** Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan Inc. is an indirect wholly owned subsidiary of Mylan N.V. Defendants further admit that Mylan GmbH is an indirect wholly-owned subsidiary of Mylan N.V. Defendants deny all remaining allegations of Paragraph 9.

10. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc.

**ANSWER:** Admitted.

11. Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in the Commonwealth of Pennsylvania and throughout the United States.

**ANSWER:** Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

## NATURE OF THE ACTION

12. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act of 2009 ("the BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (amending, inter alia, 35 U.S.C. § 271 and 42 U.S.C. § 262).

**ANSWER:** Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that this is an action for alleged patent infringement. Defendants deny all remaining allegations of Paragraph 12.

13. The asserted patents are U.S. Patent No. 8,273,707 ("the '707 Patent") and U.S. Patent No. 9,643,997 ("the '997 Patent"). Amgen is the owner of all rights, title, and interest in the '707 and '997 Patents. The '707 and '997 Patents claim methods of purifying proteins used in the manufacture of a biological product.

**ANSWER:** Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the electronic records of the United States Patent and Trademark Office ("PTO") identify Amgen Inc. as the purported "assignee" of U.S. Patent Nos. 9,643,997 B2 ("the '997 patent") and 8,273,707 B2 ("the '707 patent"). Defendants deny all remaining allegations of Paragraph 13.

14. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). The abbreviated pathway (also known as "the subsection (k) pathway") allows a biosimilar applicant (here, Mylan GmbH, acting in concert with the other Defendants) to rely on the prior licensure and approval status of the innovative biological product (here, NEULASTA®) that the biosimilar purports to copy. Amgen is the sponsor of the reference product ("reference product sponsor" or "RPS"), NEULASTA®, which is approved by FDA to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. Under the subsection (k) pathway, the biosimilar applicant may rely on its reference product's data rather than demonstrating that a biological product is safe, pure, and potent, as Amgen was required to do to obtain FDA licensure of its reference product under 42 U.S.C. § 262(a).

**ANSWER:** Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Biologics Price Competition and Innovation Act ("BPCIA") created an abbreviated approval process for biosimilar products that are "highly similar to the reference product" and exhibit "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i); *see also* 42 U.S.C. § 262(k). Defendants further admit that Mylan GmbH's BLA seeks approval of MYL-1401H Solution for Subcutaneous

Injection, a proposed biosimilar to NEULASTA® ("Mylan GmbH's Proposed BLA Product"). Defendants further admit that FDA's electronic records identify Amgen Inc. in connection with BLA No. 125031 for NEULASTA® (Pegfilgrastim) Injection. Defendants deny all remaining allegations of Paragraph 14.

15. To avoid burdening the courts and parties with unnecessary disputes, the BPCIA also creates an intricate and carefully orchestrated set of procedures for the biosimilar applicant and the RPS to engage in a series of information exchanges and good-faith negotiations between parties prior to the filing of a patent infringement lawsuit. These exchanges are set forth in 42 U.S.C. § 262(*l*)(2)-(*l*)(5) and culminate in an "immediate patent infringement action" pursuant to 42 U.S.C. § 262(*l*)(6).

**ANSWER:** Paragraph 15 contains legal conclusions to which no answer is required. To the extent answer is required, Defendants admit that "[t]he BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017) (citing 42 U.S.C. § 262(*l*)). Defendants further admit that the BPCIA scheme includes multiple steps, including disclosure of information, potential resolution of patent disputes, and if necessary and appropriate, the commencement of a patent infringement action. Defendants deny all remaining allegations of Paragraph 15.

16. Seeking the benefits of the subsection (k) pathway, Mylan GmbH, acting in concert with the other Defendants, submitted Defendants' abbreviated Biologics License Application No. 761075 (the "Mylan aBLA") to FDA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k), requesting that its biological product ("the Mylan Pegfilgrastim Product") be licensed by relying on Amgen's demonstration that NEULASTA® (pegfilgrastim) is "safe, pure, and potent."

**ANSWER:** Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, pursuant to 42 U.S.C. § 262(k), Mylan GmbH submitted its BLA to FDA seeking approval of Mylan GmbH's Proposed BLA Product. Defendants deny all remaining allegations of Paragraph 16.

17. Upon information and belief Mylan GmbH, acting in concert with the other Defendants, submitted the Mylan aBLA to FDA prior to February 2017, and thus before the expirations of the '707 Patent and the '997 Patent.

**ANSWER:** Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH submitted its BLA to FDA prior to February 2017. Defendants deny all remaining allegations of Paragraph 17.

18. Upon information and belief, Defendants received FDA acceptance of the Mylan aBLA for review on or about February 7, 2017.

**ANSWER:** Defendants admit that FDA notified Mylan GmbH that its BLA had been accepted for review on or about February 7, 2017.

19. In March 2017, the parties began exchanging information as required by the BPCIA.

**ANSWER:** Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that on March 2, 2017, pursuant to 42 U.S.C. § 262(*l*)(2)(A), Mylan GmbH provided all representatives identified by Amgen, pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii), a copy of Mylan GmbH's BLA in its entirety, along with information that describes the process or processes used to manufacture Mylan GmbH's Proposed BLA Product.

20. The '707 Patent was included on Amgen's May 1, 2017 disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pursuant to 42 U.S.C. § 262(*l*)(7), the '997 Patent was included on Amgen's June 7, 2017 supplement to its 42 U.S.C. § 262(*l*)(3)(A) list.

**ANSWER:** Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that in a letter dated May 1, 2017, Amgen identified the '707 patent pursuant to 42 U.S.C. § 262(*l*)(3)(A). Defendants further admit that in a letter dated June 7, 2017, Plaintiffs stated that "[p]ursuant to 42 U.S.C. § 262(*l*)(7), Amgen hereby supplements the list that Amgen provided to Mylan under 42 U.S.C. § 262(*l*)(3)(A)" to include the '997 patent. Defendants deny all remaining allegations of Paragraph 20.

21. Under 35 U.S.C. § 271(e)(2)(C)(i), it is an act of infringement to submit an application seeking approval of a biological product with respect to patents identified in the lists of patents described in 42 U.S.C. § 262(*l*)(3) if the purpose of such submission is to obtain

approval to engage in the commercial manufacture, use, or sale of a biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. *See Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1672 (2017).

**ANSWER:** Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit 35 U.S.C. § 271(e)(2)(C) states that:

> "It shall be an act of infringement to submit" an application seeking approval of a biological product "with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act) . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

Defendants deny all remaining allegations of Paragraph 21.

22. Here, Defendants committed an act of infringement with respect to each of the '707 and '997 Patents under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Mylan GmbH to submit the Mylan aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product.

**ANSWER:** Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that Mylan GmbH submitted its BLA to FDA seeking approval of Mylan GmbH's Proposed BLA Product. Defendants deny all remaining allegations of Paragraph 22.

23. If FDA approves the Mylan aBLA and Defendants import the Mylan Pegfilgrastim Product into the United States, or offer to sell, sell, or use the Mylan Pegfilgrastim Product within the United States, Defendants will also infringe one or more claims of the '707 and '997 Patents under 35 U.S.C. § 271(g).

**ANSWER:** Denied.

## JURISDICTION AND VENUE

24. This action arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code.

**ANSWER:** Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that this is an action for alleged patent infringement. Defendants further admit that subject matter jurisdiction is proper only for the claims directed solely against Mylan GmbH under 35 U.S.C § 271(e)(2)(C)(i). Defendants deny that subject matter jurisdiction is proper as to Mylan N.V., Mylan Inc. and MPI. Defendants deny all remaining allegations of Paragraph 24.

25. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that subject matter jurisdiction is proper only for the claims directed solely against Mylan GmbH. Defendants deny that subject matter jurisdiction is proper as to Mylan N.V., Mylan Inc. and MPI. Defendants deny all remaining allegations of Paragraph 25.

26. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

**ANSWER:** Paragraph 26 contains legal conclusions to which no answer is required. Defendants deny that Mylan N.V., Mylan Inc. and MPI are proper parties to this action. To the extent an answer is required, denied.

27. Upon information and belief, Mylan Pharmaceuticals Inc. has a regular and established place of business in Pennsylvania. Upon information and belief, Mylan Pharmaceuticals Inc. is licensed to do business in Pennsylvania as a foreign business corporation.

**ANSWER:** Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that MPI is a foreign corporation that is licensed

to do business in Pennsylvania. Defendants deny that MPI is a proper party to this action. Defendants deny all remaining allegations of Paragraph 27.

28. This Court has personal jurisdiction over each of the Defendants for the reasons set forth below.

**ANSWER:** Paragraph 28 contains legal conclusions to which no answer is required. Defendants deny that Mylan N.V., Mylan Inc. and MPI are proper parties to this action. Defendants deny all remaining allegations of Paragraph 28.

**A. Mylan Inc.**

29. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

**ANSWER:** Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

30. This Court has personal jurisdiction over Mylan Inc. by virtue of, among other things, Mylan Inc. being a Pennsylvania corporation; having its principal place of business in Canonsburg, Pennsylvania; having availed itself of the rights and benefits of Pennsylvania law; and having engaged in substantial and continuing contacts with Pennsylvania.

**ANSWER:** Paragraph 30 contains legal conclusions to which no answer is required. Defendants deny that Mylan Inc. is a proper party to this action. To the extent an answer is required, admitted.

**B. Mylan Pharmaceuticals Inc.**

31. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

**ANSWER:** Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

32. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc., which exercises considerable control over Mylan Pharmaceuticals Inc.

**ANSWER:** Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that MPI is a wholly owned subsidiary of Mylan Inc. Defendants deny all remaining allegations of Paragraph 32.

33. Upon information and belief, Mylan Pharmaceuticals Inc. develops, manufactures, seeks regulatory approval for, markets, distributes, and sells biopharmaceuticals for sale and use throughout the United States, including in Pennsylvania and this federal judicial District.

**ANSWER:** Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that MPI's business concerns pharmaceutical products, including high-quality generic medicines. Defendants deny all remaining allegations of Paragraph 33.

34. This Court has personal specific jurisdiction over Mylan Pharmaceuticals Inc. because, upon information and belief, following any FDA approval of the Mylan Pegfilgrastim Product, Mylan Pharmaceuticals Inc. will sell the Mylan Pegfilgrastim Product that is the subject of the patent infringement claims in this action in Pennsylvania and throughout the United States.

**ANSWER:** Paragraph 34 contains legal conclusions to which no answer is required. Defendants deny that MPI is a proper party to this action. Defendants deny all remaining allegations of Paragraph 34.

35. This Court has personal general jurisdiction over Mylan Pharmaceuticals Inc. by virtue of, inter alia, its having conducted business in this District, having availed itself of the rights and benefits of Pennsylvania law, and having engaged in substantial and continuing contacts with Pennsylvania. Upon information and belief, Mylan Pharmaceuticals Inc. has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in Pennsylvania and this District. In addition, Mylan Pharmaceuticals Inc. has availed itself of this Court by asserting claims in this District, *see, e.g.*, *Mylan Inc., Mylan Pharmaceuticals, Inc. v. Boehringer Ingelheim International GmbH, et al.*, Case No. 09-00990-GLL (W.D. Pa. complaint filed July 7, 2009), and by asserting counterclaims against plaintiffs in this judicial District and by consenting to this Court as a patent infringement defendant, *see, e.g.*, *Takeda Pharmaceutical Company Limited, et al. v. Mylan Inc., Mylan Pharmaceuticals Inc.*, Case No. 12-00026-AJS (W.D. Pa. answer and counterclaims filed Jan. 23, 2012).

**ANSWER:** Paragraph 35 contains legal conclusions to which no answer is required. Defendants deny that MPI is a proper party to this action. Defendants deny all remaining allegations of Paragraph 35.

**C. Mylan GmbH**

36. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

**ANSWER:** Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

37. Upon information and belief, Mylan GmbH collaborates with Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan N.V. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in Pennsylvania and in the United States.

**ANSWER:** Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH's business includes seeking regulatory approval for high-quality biopharmaceutical drugs. Defendants deny all remaining allegations of Paragraph 37.

38. Upon information and belief, Mylan GmbH operates as a subsidiary of Mylan N.V., which exercises considerable control over Mylan GmbH.

**ANSWER:** Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH is an indirect wholly owned subsidiary of Mylan N.V. Defendants deny all remaining allegations of Paragraph 38.

39. This Court has personal specific jurisdiction over Mylan GmbH because, upon information and belief, Mylan GmbH submitted the Mylan aBLA seeking approval from FDA to market and sell the Mylan Pegfilgrastim Product in the Commonwealth of Pennsylvania and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement.

**ANSWER:** Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

40. Further, upon information and belief, Mylan GmbH has or will directly or indirectly manufacture, import into the United States, and/or sell the Mylan Pegfilgrastim Product that is the subject of the infringement claim in this action in Pennsylvania and throughout the United States.

**ANSWER:** Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

41. Additionally, upon information and belief, Mylan GmbH exercises considerable control over Mylan Inc. and Mylan Pharmaceuticals Inc. with respect to biosimilar products, and approves significant decisions of Mylan Inc. and Mylan Pharmaceuticals Inc. such as allowing Mylan Inc. and Mylan Pharmaceuticals Inc. to act as United States agents in connection with preparing and submitting the Mylan aBLA.

**ANSWER:** Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

42. Additionally, and in the alternative, Plaintiffs allege that to the extent Mylan GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the Commonwealth of Pennsylvania, Mylan GmbH likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

**ANSWER:** Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

**D. Mylan N.V.**

43. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

**ANSWER:** Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

44. Upon information and belief, Mylan N.V. collaborates with Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan GmbH to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in Pennsylvania and in the United States.

**ANSWER:** Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

45. Upon information and belief, Mylan GmbH operates as a subsidiary of Mylan N.V., which exercises considerable control over Mylan GmbH.

**ANSWER:** Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH is an indirect wholly owned subsidiary of Mylan N.V. Defendants deny all remaining allegations of Paragraph 45.

46. Mylan N.V. has issued at least one press release regarding the Mylan Pegfilgrastim Product and its regulatory status. *See* Press Release, Mylan N.V., "U.S. FDA Accepts Biologics License Application (BLA) for Mylan and Biocon's Proposed Biosimilar Pegfilgrastim for Review" (Feb. 16, 2017), http://newsroom.mylan.com/2017-02-16-U-S-FDA-Accepts-Biologics-License-Application-BLA-for-Mylan-and-Biocons-Proposed-Biosimilar-Pegfilgrastim-for-Review, attached hereto as Exhibit 1.

**ANSWER:** Defendants admit that Mylan N.V. issued a press release dated February 16, 2017 titled "U.S. FDA Accepts Biologics License Application (BLA) for Mylan and Biocon's Proposed Biosimilar Pegfilgrastim for Review" a copy of which appears to be attached to the Complaint as Exhibit 1.

47. According to the Defendants' website (page attached hereto as Exhibit 2) "[t]he Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania."

**ANSWER:** Defendants admit that the web page http://www.mylan.com/en/company/corporate-governance, a copy of which appears to be attached to the Complaint as Exhibit 2, dated September 22, 2017, states:

> [t]he Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania.

48. This Court has personal jurisdiction over Mylan N.V. by virtue of, among other things, Mylan N.V. having its global headquarters and principal offices in Canonsburg,

Pennsylvania; having availed itself of the rights and benefits of Pennsylvania law; and having engaged in substantial and continuing contacts with Pennsylvania.

**ANSWER:** Paragraph 48 contains legal conclusions to which no answer is required. Defendants deny that Mylan N.V. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 48.

49. Additionally, this Court has personal specific jurisdiction over Mylan N.V. because, upon information and belief, the acts of Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan GmbH complained of herein were done, in part, for the benefit of Mylan N.V. Further, upon information and belief, Mylan N.V. has or will directly or indirectly manufacture, import into the United States, and/or sell the Mylan Pegfilgrastim Product that is the subject of the infringement claim in this action in Pennsylvania and throughout the United States.

**ANSWER:** Paragraph 49 contains legal conclusions to which no answer is required. Defendants deny that Mylan N.V. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 49.

50. Additionally, upon information and belief, Mylan N.V. exercises considerable control over Mylan Inc. and Mylan Pharmaceuticals Inc. with respect to biosimilar products, and approves significant decisions of Mylan Inc. and Mylan Pharmaceuticals Inc. such as allowing Mylan Inc. and Mylan Pharmaceuticals Inc. to act as United States agents in connection with preparing and submitting the Mylan aBLA.

**ANSWER:** Paragraph 50 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

51. Additionally, and in the alternative, Plaintiffs allege that to the extent Mylan N.V. is not subject to the jurisdiction of the courts of general jurisdiction of the Commonwealth of Pennsylvania, Mylan N.V. likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

**ANSWER:** Paragraph 51 contains legal conclusions to which no answer is required. Defendants deny that Mylan N.V. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 51.

## BACKGROUND

52. Amgen is one of the world's leading biopharmaceutical companies and is dedicated to using discoveries in human biology to invent, develop, manufacture, and sell new therapeutic products for the benefit of patients suffering from serious illnesses. Toward that end, Amgen has invested billions of dollars into its research and development efforts.

**ANSWER:** Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 52, and therefore deny all such allegations.

53. In 2002, Amgen introduced NEULASTA® (pegfilgrastim), an innovative biologic medicine which has benefited millions of cancer patients as a treatment of side effects of certain forms of cancer therapy. Amgen conducted extensive clinical trials and submitted the results of those trials to FDA in order to prove that NEULASTA® is safe, pure, and potent.

**ANSWER:** Paragraph 53 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that according to FDA's electronic records, and specifically FDA's "Purple Book," NEULASTA® was approved on January 31, 2002. Defendants further admit that FDA's electronic records identify Amgen Inc. in connection with BLA No. 125031 for NEULASTA® (Pegfilgrastim) Injection. Defendants deny all remaining allegations of Paragraph 53.

54. The active ingredient in Amgen's innovative NEULASTA® product is pegfilgrastim, a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor ("G-CSF") conjugated to a 20 kD monomethoxypolyethylene glycol (m-PEG) at the N-terminus of G-CSF.

**ANSWER:** Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that according to FDA's electronic records, the active ingredient in NEULASTA® is pegfilgrastim. Further answering, Defendants admit that, according to the currently approved label for NEULASTA®, available at Drugs@FDA:

> Neulasta (pegfilgrastim) is a covalent conjugate of recombinant methionyl human G-CSF (filgrastim) and monomethoxypolyethylene glycol. Filgrastim is a water-soluble 175 amino acid protein with a molecular weight of approximately 19 kilodaltons (kD). Filgrastim is obtained from the bacterial fermentation of a strain of *E coli* transformed with a genetically

> engineered plasmid containing the human G-CSF gene. To produce pegfilgrastim, a 20 kD monomethoxypolyethylene glycol molecule is covalently bound to the N-terminal methionyl residue of filgrastim.

Defendants deny all remaining allegations of Paragraph 54.

55. NEULASTA® is indicated to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. By binding to specific receptors on the surface of certain types of cells, NEULASTA® stimulates the production of a type of white blood cells known as neutrophils. Neutrophils are the most abundant type of white blood cells and form a vital part of the human immune system. A deficiency in neutrophils is known as neutropenia, a condition which makes the individual highly susceptible to infection. Neutropenia can result from a number of causes; it is a common side effect of chemotherapeutic drugs used to treat certain forms of cancer. NEULASTA® counteracts neutropenia.

**ANSWER:** Paragraph 55 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that according to the currently approved label:

> Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Defendants deny all remaining allegations of Paragraph 55.

56. NEULASTA® represented a major advance in cancer treatment by protecting chemotherapy patients from the harmful effects of neutropenia and by facilitating more effective chemotherapy regimens.

**ANSWER:** Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 56, and therefore deny all such allegations.

57. Prior to 2010, any other company wishing to sell its own version of NEULASTA® would have had to undertake the same extensive effort to conduct clinical trials to prove to FDA that its proposed version was also safe, pure, and potent.

**ANSWER:** Paragraph 57 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the BPCIA was enacted on March 23, 2010 as part of the Patient Protection and Affordable Care Act (Pub. L. No. 111-148). Further

answering, Defendants admit that the BPCIA altered the way that certain biological products are approved and regulated. Defendants deny all remaining allegations of Paragraph 57.

58. Developing a new therapeutic product from scratch is extremely expensive: studies estimate the cost of obtaining FDA approval of a new biologic product at more than $2.5 billion. *See* DiMasi J.A. *et al.*, Innovation in the pharmaceutical industry: New estimates of R&D costs, 47 J. Health Econ. 20, 25-26 (2016), attached hereto as Exhibit 3.

**ANSWER:** Defendants admit that what purports to be a copy of J. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016) is attached to the Complaint as Exhibit 3. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 58, and therefore deny all such allegations.

59. Upon information and belief, Mylan GmbH, acting in concert with the other Defendants, submitted the Mylan aBLA with FDA pursuant to Section 351(k) of the Public Health Service Act in order to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States the Mylan Pegfilgrastim Product, a biosimilar version of Plaintiffs' NEULASTA® (pegfilgrastim) product.

**ANSWER:** Paragraph 59 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH submitted its BLA to FDA pursuant to 42 U.S.C. § 262(k) seeking approval for Mylan GmbH's Proposed BLA Product, a proposed biosimilar to NEULASTA®. Defendants deny all remaining allegations of Paragraph 59.

60. Upon information and belief, the Mylan aBLA references and relies on the approval and licensure of Plaintiffs' NEULASTA® (pegfilgrastim) product in support of Defendants' request for FDA approval.

**ANSWER:** Paragraph 60 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit Mylan GmbH's BLA identifies NEULASTA® BLA No. 125031 as the "reference listed drug." Further answering, Defendants admit that

FDA's electronic records identify Amgen Inc. in connection with BLA No. 125031 for NEULASTA®. Defendants deny all remaining allegations of Paragraph 60.

61. Upon information and belief, the Mylan Pegfilgrastim Product is designed to copy and compete with Plaintiffs' NEULASTA® (pegfilgrastim).

**ANSWER:** Paragraph 61 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

62. Upon information and belief, Defendants did not seek to independently demonstrate to FDA that their biological product is "safe, pure, and potent" pursuant to 42 U.S.C. § 262(a), as Amgen did in its BLA for its innovative biological product NEULASTA® (pegfilgrastim). Rather, upon information and belief, Defendants requested that FDA evaluate the suitability of their biological product for licensure, expressly electing and seeking reliance on Amgen's FDA license for NEULASTA® (pegfilgrastim). Accordingly, Defendants submitted to FDA publicly available information regarding FDA's previous licensure determination that NEULASTA® (pegfilgrastim) is "safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I).

**ANSWER:** Paragraph 62 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH submitted its BLA to FDA pursuant to 42 U.S.C. § 262(k) seeking approval for Mylan GmbH's Proposed BLA Product, a proposed biosimilar to NEULASTA®. Defendants deny all remaining allegations of Paragraph 62.

63. Defendants are piggybacking on the fruits of Plaintiffs' trailblazing efforts. Defendants have publicly announced that they submitted the Mylan aBLA under the subsection (k) pathway to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States the Mylan Pegfilgrastim Product that they assert is a biosimilar version of Plaintiffs' NEULASTA®. *See* Press Release, Mylan N.V., "U.S. FDA Accepts Biologics License Application (BLA) for Mylan and Biocon's Proposed Biosimilar Pegfilgrastim for Review" (Feb. 16, 2017), http://newsroom.mylan.com/2017-02-16-U-S-FDA-Accepts-Biologics-License-Application-BLA-for-Mylan-and-Biocons-Proposed-Biosimilar-Pegfilgrastim-for-Review, attached hereto as Exhibit 1.

**ANSWER:** Paragraph 63 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH submitted its BLA to FDA pursuant to 42 U.S.C. § 262(k) seeking approval for Mylan GmbH's Proposed BLA Product, a

proposed biosimilar to NEULASTA®. Defendants deny all remaining allegations of Paragraph 63.

64. In March 2017, the exchange of information between Amgen and Mylan GbmH, as required by the BPCIA, began.

**ANSWER:** Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, pursuant to 42 U.S.C. § 262(*l*)(2), on February 17, 2017, Mylan GmbH provided notice of FDA's acceptance for review of Mylan GmbH's BLA to Amgen Inc., identified by Drugs@FDA as the reference product sponsor of BLA No. 125031 for NEULASTA®. Defendants further admit that on March 2, 2017, pursuant to 42 U.S.C. § 262(*l*)(2)(A), Mylan GmbH provided all representatives identified by Amgen, pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii), a copy of Mylan GmbH's BLA in its entirety, along with information that describes the process or processes used to manufacture Mylan GmbH's Proposed BLA Product. Defendants deny all remaining allegations of Paragraph 64.

65. On March 2, 2017, pursuant to 42 U.S.C. § 262(*l*)(2)(A), Mylan GmbH provided Amgen's counsel with access to the Mylan aBLA.

**ANSWER:** Defendants admit that on March 2, 2017, pursuant to 42 U.S.C. § 262(*l*)(2)(A), Mylan GmbH provided all representatives identified by Amgen, pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii), a copy of Mylan GmbH's BLA in its entirety, along with information that describes the process or processes used to manufacture Mylan GmbH's Proposed BLA Product.

66. Upon information and belief, the Mylan aBLA provided to Amgen was in a format different than and less complete than the format provided to FDA.

**ANSWER:** Paragraph 66 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH provided all representatives identified by Amgen, pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii), a copy of Mylan GmbH's BLA in its entirety, along with information that describes the process or processes used to manufacture

Mylan GmbH's Proposed BLA Product. Defendants further admit that beginning on March 2, 2017, all representatives identified by Amgen, pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii), had access to a searchable, hyperlinked, electronic copy of Mylan GmbH's BLA in a format that among other attributes, was (1) fully searchable across the entire text of Mylan GmbH's BLA, (2) maintained all hyperlinks both within each document and as linked to any other documents in Mylan GmbH's BLA, (3) maintained the folder and sub folder structure and modules as submitted to FDA, with each module placed in the appropriate folder, (4) followed FDA's eCTD technical specification Table of Contents ("TOC") Headings and Hierarchy, which maintains the hyperlinked TOC navigation in BLA applications, and (5) maintained all the folder naming conventions so that materials are conventionally named as provided to FDA, among other things. Defendants deny all remaining allegations of Paragraph 66.

67. Upon information and belief, the Mylan aBLA was provided to FDA in Electronic Common Technical Document (eCTD) format with fully working hyperlinks and without restrictions on, inter alia, viewing, copying, and printing.

**ANSWER:** Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH's BLA complied with FDA's electronic submission requirements. Defendants deny all remaining allegations of Paragraph 67.

68. Mylan GmbH's failure to provide "a copy of the application submitted to the Secretary under subsection (k)" as required by 42 U.S.C. § 262(*l*)(2)(A) materially prejudiced and impeded Amgen's ability to review the Mylan aBLA. For example: Mylan GmbH uploaded the Mylan aBLA to a virtual data room (the "ShareVault data room") and provided Amgen's counsel with credentials to access the documents and data on the ShareVault data room. Mylan GmbH configured the ShareVault data room to prohibit Amgen from, inter alia, saving, copying, annotating, or printing any documents or data on the ShareVault data room. The ShareVault data room is also slow and cumbersome, and lacks fully working hyperlinks. In addition, Amgen was and, in some cases, continues to be unable to view many of the documents and data on the ShareVault data room, including many of the xml, xsl, sas, xpt, jpeg, and txt files. Additionally, the ShareVault data room suffered periodic technological failures, preventing Amgen from accessing or viewing the documents and data on the ShareVault data room.

**ANSWER:** Paragraph 68 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH provided all representatives identified by Amgen, pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii), a copy of Mylan GmbH's BLA in its entirety, along with information that describes the process or processes used to manufacture Mylan GmbH's Proposed BLA Product, utilizing ShareVault, a secure data room provider. Defendants further admit that beginning on March 2, 2017, all representatives identified by Amgen, pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii), had access to a searchable, hyperlinked, electronic copy of Mylan GmbH's BLA in its entirety. Defendants deny all remaining allegations of Paragraph 68.

69. Mylan GmbH also failed to provide "other information that describes the process or processes used to manufacture the biological product that is the subject of" the Mylan aBLA, pursuant to 42 U.S.C. § 262(*l*)(2)(A). In April and May 2017, Amgen requested certain specific categories of documents that it believes exist and describe the Defendants' process for manufacturing the Mylan Pegfilgrastim Product. Mylan GmbH undertook to consider Amgen's request but, to date, has failed to provide such documents.

**ANSWER:** Paragraph 69 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that on March 2, 2017, Mylan GmbH provided all representatives identified by Amgen, pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii)(I), access to over 175,000 pages of information, including hundreds of pages of other manufacturing information beyond what is found in Mylan GmbH's BLA, which "describe[] the process or processes used to manufacture the biological product that is the subject of such application," 42 U.S.C. § 262(*l*)(2)(A), including those "categories of documents" identified in Amgen's April 24, 2017 correspondence. Defendants deny all remaining allegations of Paragraph 69.

70. On May 1, 2017, Amgen provided Mylan GmbH with Amgen's list of patents under 42 U.S.C. § 262(*l*)(3)(A). That list included the '707 Patent and U.S. Patent No. 8,940,878 ("the '878 Patent"). On June 5, 2017, Mylan GmbH provided its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases of Mylan GmbH's opinions that the '707 and '878 Patents are invalid, are unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA.

**ANSWER:** Paragraph 70 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that on May 1, 2017, Amgen identified U.S. Patent No. 8,940,878 ("the '878 patent") and the '707 patent pursuant to 42 U.S.C. § 262(*l*)(3)(A). Further answering, Defendants admit that on June 5, 2017, Mylan GmbH provided its detailed statements pursuant to 42 U.S.C. § 262(*l*)(3)(B), which described on a claim-by-claim basis the factual and legal bases of Mylan GmbH's opinion that the '878 and '707 patents are invalid, unenforceable, and/or will not be infringed by Mylan GmbH's Proposed BLA Product. Defendants deny all remaining allegations of Paragraph 70.

71. On June 7, 2017, pursuant to 42 U.S.C. § 262(*l*)(7) Amgen supplemented its 42 U.S.C. § 262(*l*)(3)(A) list to include the '997 Patent. On June 9, 2017, Mylan GmbH provided a detailed statement pursuant to 42 U.S.C. § 262(*l*)(7) describing the factual and legal bases of Mylan GmbH's opinions that the '997 Patent is invalid, is unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA.

**ANSWER:** Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that on June 7, 2017, Amgen stated that "[p]ursuant to 42 U.S.C. § 262(*l*)(7), Amgen hereby supplements the list that Amgen provided to Mylan under 42 U.S.C. § 262(*l*)(3)(A)" to include the '997 patent. Further answering, Defendants admit that on June 9, 2017, Mylan GmbH provided its detailed statement pursuant to 42 U.S.C. § 262(*l*)(7)(B), which described on a claim-by-claim basis the factual and legal bases of Mylan GmbH's opinion that the '997 patent is invalid, unenforceable, and/or will not be infringed by Mylan GmbH's Proposed BLA Product. Defendants deny all remaining allegations of Paragraph 71.

72. On August 4, 2017, Amgen provided its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) describing the factual and legal bases of Amgen's opinion that certain claims of the '707 and '878 Patents will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA, and Amgen's responses to the invalidity and unenforceability assertions against the '707 and '878 Patents in Mylan GmbH's statement under 42 U.S.C. § 262(*l*)(3)(B).

**ANSWER:** Paragraph 72 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that in August 4, 2017 correspondence, Amgen purported to provide Amgen's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) with respect to the '707 and '878 patents. Defendants deny all remaining allegations of Paragraph 72.

73. On August 8, 2017, Amgen provided Mylan GmbH with the factual and legal bases of Amgen's opinion that certain claims of the '997 will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA and responses to the invalidity and unenforceability assertions against the '997 Patent in Mylan GmbH's June 9, 2017 statement.

**ANSWER:** Paragraph 73 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that in August 8, 2017 correspondence, Amgen purported to provide a "statement regarding U.S. Patent No. 9,643,997." Defendants deny all remaining allegations of Paragraph 73.

74. Amgen and Mylan GmbH then negotiated under 42 U.S.C. § 262(*l*)(4) as to "which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6)." Failing to reach agreement, Amgen and Mylan GmbH exchanged lists pursuant to the procedures of 42 U.S.C. § 262(*l*)(5) on August 25, 2017. Amgen asserted that there should be an immediate patent infringement action on the '707 and '997 Patents, but not on the '878 Patent.

**ANSWER:** Paragraph 74 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that in August 7, 2017 correspondence, Mylan GmbH consented to immediate patent infringement litigation pursuant to 42 U.S.C. § 262(*l*)(6) on the '707 patent, the '997 patent and the '878 patent and otherwise began negotiations pursuant to 42 U.S.C. § 262(*l*)(4) as to "which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6)." Further answering, Defendants admit that Mylan GmbH and Amgen exchanged patent lists pursuant to 42 U.S.C. § 262(*l*)(5)(B) on August 25, 2017. Defendants further admit that Amgen asserted that there should be an immediate patent

infringement action on the '707 and '997 patents, but at that time Amgen did not intend to pursue suit on the '878 patent. Defendants deny all remaining allegations of Paragraph 74.

75. Accordingly, Plaintiffs now file this immediate patent infringement action against Defendants pursuant to 42 U.S.C. § 262(*l*)(6)(B) on the '707 and '997 Patents. This action follows "not later than 30 days after the exchange of lists under paragraph (5)(B)."

**ANSWER:** Paragraph 75 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, pursuant to 42 U.S.C. § 262(*l*)(6)(B) and "not later than 30 days after the exchange of lists under paragraph (5)(B)," Plaintiffs filed this action for alleged patent infringement of the '707 and '997 patents. Defendants deny all remaining allegations of Paragraph 75.

**THE PATENTS-IN-SUIT: U.S. PATENT NOS. 8,273,707 AND 9,643,997**

76. Amgen is the owner of all rights, title, and interest in the '707 Patent.

**ANSWER:** Paragraph 76 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the electronic records of the PTO identify Amgen Inc. as the purported "assignee" of the '707 patent. Defendants deny all remaining allegations of Paragraph 76.

77. AML is the exclusive licensee under the '707 Patent.

**ANSWER:** Paragraph 77 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 77, and therefore deny all such allegations.

78. The '707 Patent, titled "Process For Purifying Proteins," was duly and legally issued on September 25, 2012 by the U.S. Patent and Trademark Office. A true and correct copy of the '707 Patent is attached to this Complaint as Exhibit 4.

**ANSWER:** Paragraph 78 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, according to the electronic records of the

PTO, on or about September 25, 2012, the PTO issued the '707 patent, titled "PROCESS FOR PURIFYING PROTEINS," and that what purports to be a copy of the '707 patent is attached to the Complaint as Exhibit 4. Defendants deny that the '707 patent was "duly and legally issued," and any suggestion or implication that the '707 patent is valid or enforceable. Defendants deny all remaining allegations of Paragraph 78.

79. The '707 Patent is directed to a process for purifying proteins.

**ANSWER:** Paragraph 79 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

80. Amgen is the owner of all rights, title, and interest in the '997 Patent.

**ANSWER:** Paragraph 80 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the electronic records of the PTO identify Amgen Inc. as the purported "assignee" of the '997 patent. Defendants deny all remaining allegations of Paragraph 80.

81. AML is the exclusive licensee under the '997 Patent.

**ANSWER:** Paragraph 81 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 81, and therefore deny all such allegations.

82. The '997 Patent, titled "Capture Purification Processes for Proteins Expressed in a Non-Mammalian System," was duly and legally issued on May 9, 2017 by the U.S. Patent and Trademark Office. A true and correct copy of the '997 Patent is attached to this Complaint as Exhibit 5.

**ANSWER:** Paragraph 82 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, according to the electronic records of the PTO, on or about May 9, 2017, the PTO issued the '997 patent, titled "CAPTURE

PURIFICATION PROCESSES FOR PROTEINS EXPRESSED IN A NON-MAMMALIAN SYSTEM," and that what purports to be a copy of the '997 patent is attached to the Complaint as Exhibit 5. Defendants deny that the '997 patent was "duly and legally issued," and any suggestion or implication that the '997 patent is valid or enforceable. Defendants deny all remaining allegations of Paragraph 82.

83. The '997 Patent is directed to a process for purifying proteins.

**ANSWER:** Paragraph 83 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

## CAUSES OF ACTION

### FIRST COUNT:
### '707 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(i)

84. Amgen incorporates by reference paragraphs 1-83 as if fully set forth herein.

**ANSWER:** Defendants restate and incorporate by reference their answers to Paragraphs 1 through 83 as though fully set forth herein.

85. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product, a proposed biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

**ANSWER:** Defendants admit that, pursuant to 42 U.S.C. § 262(k), Mylan GmbH submitted its BLA to FDA seeking approval of Mylan GmbH's Proposed BLA Product. Defendants deny all remaining allegations of Paragraph 85.

86. Defendants committed an act of infringement with respect to the '707 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Mylan GmbH to submit the Mylan aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product.

**ANSWER:** Denied.

87. Upon information and belief, Defendants intend to manufacture, use, sell, and/or offer for sale within the United States, and/or import into the United States, the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

**ANSWER:** Paragraph 87 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH submitted its BLA to FDA seeking approval of Mylan GmbH's Proposed BLA Product prior to the natural expiration of the '707 patent. Defendants deny all remaining allegations of Paragraph 87.

88. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan Pegfilgrastim Product will infringe, literally or under the doctrine of equivalents, one or more claims of the '707 Patent.

**ANSWER:** Denied.

89. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Amgen has provided Defendants with a detailed statement describing with respect to the '707 Patent, on a claim by claim basis, the factual and legal bases of Amgen's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA. Amgen's detailed statement includes, refers to, and relies on confidential information that Mylan GmbH provided to Amgen pursuant to 42 U.S.C. § 262(*l*)(2). Amgen does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Amgen is not permitted to include confidential information provided by Mylan GmbH "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

**ANSWER:** Paragraph 89 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that in August 4, 2017 correspondence, Amgen purported to provide Amgen's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) with respect to the '707 patent. Defendants further admit that, pursuant to 42 U.S.C. § 262(*l*)(1)(F), Plaintiffs are not permitted to include confidential information provided by Mylan GmbH "in any publicly-available complaint or other pleading." Defendants deny all remaining allegations of Paragraph 89.

90. Representative claim 1 of the '707 Patent recites:

> A process for purifying a protein on a hydrophobic interaction chromatography column such that the dynamic capacity of the column is increased for the protein comprising
>
> > mixing a preparation containing the protein with a combination of a first salt and a second salt,
> >
> > loading the mixture onto a hydrophobic interaction chromatography column, and
> > eluting the protein,
> >
> > wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and wherein the concentration of each of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0.

'707 Patent at col. 15:8-18. Upon information and belief, the process by which Defendants manufacture the Mylan Pegfilgrastim Product satisfies each limitation of at least claims 1, 2, 6, 8, 10, and 11, literally or equivalently. With respect to the requirement that the protein is purified on a hydrophobic interaction chromatography column, Defendants practice a process for purifying a protein on a hydrophobic interaction chromatography column as defined in the '707 patent. With respect to the use of a combination of a first salt and a second salt, in the Defendants' process, a preparation containing protein becomes mixed with a first salt and a second salt as recited in the claim. With respect to the salt concentration, the concentration of the salts in the Defendants' process falls within the claimed range and/or is equivalent to a concentration within the claimed range. In the Defendants' process, after the protein is loaded onto the hydrophobic interaction chromatography column in the presence of the combination of salts, the protein is eluted.

**ANSWER:** Paragraph 90 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that claim 1 of the '707 patent states:

> A process for purifying a protein on a hydrophobic interaction chromatography column such that the dynamic capacity of the column is increased for the protein comprising mixing a preparation containing the protein with a combination of a first salt and a second salt, loading the mixture onto a hydrophobic interaction chromatography column, and eluting the protein, wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and wherein the concentration of each of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0.

Defendants deny all remaining allegations of Paragraph 90.

91. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '707 Patent. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from any further infringement under 35 U.S.C. § 271(e)(4)(B).

**ANSWER:** Denied.

92. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '707 Patent will cause injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

**ANSWER:** Denied.

**SECOND COUNT:**
**'707 PATENT UNDER 35 U.S.C. § 271(g)**

93. Plaintiffs incorporate by reference paragraphs 1-92 as if fully set forth herein.

**ANSWER:** Defendants restate and incorporate by reference their answers to Paragraphs 1 through 92 as though fully set forth herein.

94. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Mylan Pegfilgrastim Product, a biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

**ANSWER:** Defendants admit that, pursuant to 42 U.S.C. § 262(k), Mylan GmbH submitted its BLA to FDA seeking approval of Mylan GmbH's Proposed BLA Product. Mylan denies all remaining allegations of Paragraph 94.

95. Upon information and belief, FDA may act upon the Mylan aBLA as soon as October 2017. FDA has stated publicly that the agency's goal is to act upon 90% of aBLA applications within 10 months of the 60-day-filing-review period that begins on the date of FDA receipt of the original aBLA submission. *See* Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, *available at* https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf.

**ANSWER:** Paragraph 95 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that FDA stated in Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, *available at* https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/

ucm521121.pdf, that it is an FDA goal to "[r]eview and act on 90 percent of original biosimilar biological product application submissions within 10 months of the 60 day filing date." Defendants deny all remaining allegations of Paragraph 95.

96. Upon information and belief, Defendants intend to, and will upon FDA licensure of the Mylan aBLA, import into the United States or offer to sell, sell, or use within the United States the Mylan Pegfilgrastim Product, which will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(g).

**ANSWER:** Denied.

97. An actual controversy has arisen and now exists between the parties concerning whether the Mylan Pegfilgrastim Product has or will infringe one or more claims of the '707 Patent.

**ANSWER:** Paragraph 97 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that there is an actual controversy concerning whether the '707 patent is infringed, valid or enforceable. Defendants deny all remaining allegations of Paragraph 97.

98. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '707 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

**ANSWER:** Denied.

99. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '707 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

**ANSWER:** Denied.

100. Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '707 Patent will cause injury to Plaintiffs, entitling them to damages under 35 U.S.C. § 284.

**ANSWER:** Denied.

**THIRD COUNT:**
**'997 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(i)**

101. Amgen incorporates by reference paragraphs 1-100 as if fully set forth herein.

**ANSWER:** Defendants restate and incorporate by reference their answers to Paragraphs 1 through 100 as though fully set forth herein.

102. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product, a proposed biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

**ANSWER:** Defendants admit that, pursuant to 42 U.S.C. § 262(k), Mylan GmbH submitted its BLA to FDA seeking approval of Mylan GmbH's Proposed BLA Product. Defendants deny all remaining allegations of Paragraph 102.

103. Defendants committed an act of infringement with respect to the '997 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Mylan GmbH to submit the Mylan aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product.

**ANSWER:** Denied.

104. Upon information and belief, Defendants intend to manufacture, use, sell, and/or offer for sale within the United States, and/or import into the United States, the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

**ANSWER:** Paragraph 104 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Mylan GmbH submitted its BLA to FDA seeking approval of Mylan GmbH's Proposed BLA Product prior to the natural expiration of the '997 patent. Defendants deny all remaining allegations of Paragraph 104.

105. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan Pegfilgrastim Product will infringe, literally or under the doctrine of equivalents, one or more claims of the '997 Patent.

**ANSWER:** Denied.

106. Amgen has provided Defendants with a statement describing with respect to the '997 Patent the factual and legal bases of Amgen's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA. Amgen's statement includes, refers to, and relies on confidential information that Mylan GmbH provided to Amgen pursuant to 42 U.S.C. § 262(*l*)(2). Amgen does not repeat its statement here because under 42 U.S.C. § 262(*l*)(1), Amgen is not permitted to include confidential information provided by Mylan GmbH "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

**ANSWER:** Paragraph 106 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that in August 8, 2017 correspondence, Amgen purported to provide a "statement regarding U.S. Patent No. 9,643,997." Defendants further admit that, pursuant to 42 U.S.C. § 262(*l*)(1)(F), Plaintiffs are not permitted to include confidential information provided by Mylan GmbH "in any publicly-available complaint or other pleading." Defendants deny all remaining allegations of Paragraph 106.

107. Representative claim 9 of the '997 Patent recites:

> A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
>
> (a) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) a reductant; and
>
> (iii) a surfactant;
>
> (b) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) an aggregation suppressor;
>
> (iii) a protein stabilizer; and
>
> (iv) a redox component;
>
> (c) applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;
>
> (d) washing the separation matrix; and
>
> (e) eluting the protein from the separation matrix.

'997 Patent at col. 22:36-55. Upon information and belief, the process by which Defendants manufacture the Mylan Pegfilgrastim Product satisfies each limitation of at least independent claim 9 and also certain dependent claims, literally or equivalently. With respect to the requirement that the protein is expressed in a non-native limited solubility form in a non-mammalian expression system, Defendants practice a process for purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system. With respect to

the requirement of the "solubilizing" step, in the Defendants' process, protein is solubilized in a solubilization solution comprising one or more of a denaturant, reductant, and surfactant. With respect to the requirement of the "forming" step, in the Defendants' process, a refold solution is formed comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of a denaturant, aggregation suppressor, protein stabilizer, and redox component. With respect to the requirement of the "applying" step, the Defendants' refold solution is applied to a separation matrix under conditions suitable for the protein to associate with the matrix. With respect to the requirement of the "washing" step, the Defendants' separation matrix is washed. With respect to the requirement of the "eluting" step, Defendants' protein is eluted from the separation matrix.

**ANSWER:** Paragraph 107 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that claim 9 of the '997 patent states:

> A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
>
> (a) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) a reductant; and
>
> (iii) a surfactant;
>
> (b) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) an aggregation suppressor;
>
> (iii) a protein stabilizer; and
>
> (iv) a redox component;
>
> (c) applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;
>
> (d) washing the separation matrix; and
>
> (e) eluting the protein from the separation matrix.

Defendants deny all remaining allegations of Paragraph 107.

108. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '997 Patent. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from any further infringement under 35 U.S.C. § 271(e)(4)(B).

**ANSWER:** Denied.

109. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of

the '997 Patent will cause injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

**ANSWER:** Denied.

**FOURTH COUNT:**
**'997 PATENT UNDER 35 U.S.C. § 271(g)**

110. Plaintiffs incorporate by reference paragraphs 1-109 as if fully set forth herein.

**ANSWER:** Defendants restate and incorporate by reference their answers to Paragraphs 1 through 109 as though fully set forth herein.

111. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Mylan Pegfilgrastim Product, a biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

**ANSWER:** Defendants admit that, pursuant to 42 U.S.C. § 262(k), Mylan GmbH submitted its BLA to FDA seeking approval of Mylan GmbH's Proposed BLA Product. Defendants deny all remaining allegations of Paragraph 111.

112. Upon information and belief, FDA may act upon the Mylan aBLA as soon as October 2017. FDA has stated publicly that the agency's goal is to act upon 90% of aBLA applications within 10 months of the 60-day-filing-review period that begins on the date of FDA receipt of the original aBLA submission. *See* Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, *available at* https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf.

**ANSWER:** Paragraph 112 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that FDA stated in Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, *available at* https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf, that it is an FDA goal to "[r]eview and act on 90 percent of original biosimilar biological product application submissions within 10 months of the 60 day filing date." Defendants deny all remaining allegations of Paragraph 112.

113. Upon information and belief, Defendants intend to, and will upon FDA licensure of the Mylan aBLA, import into the United States or offer to sell, sell, or use within the United

States the Mylan Pegfilgrastim Product, which will infringe one or more claims of the '997 Patent under 35 U.S.C. § 271(g).

**ANSWER:** Denied.

114. An actual controversy has arisen and now exists between the parties concerning whether the Mylan Pegfilgrastim Product has or will infringe one or more claims of the '997 Patent.

**ANSWER:** Paragraph 114 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that there is an actual controversy concerning whether the '997 patent is infringed, valid or enforceable. Defendants deny all remaining allegations of Paragraph 114.

115. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '997 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

**ANSWER:** Denied.

116. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '997 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

**ANSWER:** Denied.

117. Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '997 Patent will cause injury to Plaintiffs, entitling them to damages under 35 U.S.C. § 284.

**ANSWER:** Denied.

* * *

Defendants deny that Plaintiffs are entitled to any of the relief prayed for in Paragraphs (A) through (H) or to any relief whatsoever, and further request that judgment be entered in favor of the Defendants, dismissing Plaintiffs' Complaint with prejudice, awarding the Defendants

attorneys' fees and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

## SEPARATE DEFENSES

Without prejudice to the denials set forth in the Answer, without admitting any allegation of the Complaint not expressly admitted, and without assuming the burden of proof of any such defense that would otherwise rest with Plaintiffs, Defendants aver and assert the following separate defenses to the Complaint:

## FIRST DEFENSE

1. The Complaint fails to state a claim upon which relief can be granted.

## SECOND DEFENSE

2. The manufacture, use, offer to sell, sale or importation of Mylan GmbH's proposed MYL-1401H Solution for Subcutaneous Injection that is the subject of its Biologics License Application ("BLA") No. 761075, would not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of U.S. Patent No. 8,273,707 ("the '707 patent").

## THIRD DEFENSE

3. The importation, offer to sell, sale or use of Mylan GmbH's proposed MYL-1401H Solution for Subcutaneous Injection that is the subject of its BLA No. 761075, would not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '707 patent asserted under 35 U.S.C. § 271(g).

## FOURTH DEFENSE

4. The claims of the '707 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or judicially created doctrines of invalidity.

**FIFTH DEFENSE**

5. The manufacture, use, offer to sell, sale or importation of Mylan GmbH's proposed MYL-1401H Solution for Subcutaneous Injection that is the subject of its BLA No. 761075, would not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of U.S. Patent No. 9,643,997 ("the '997 patent").

**SIXTH DEFENSE**

6. The importation, offer to sell, sale or use of Mylan GmbH's proposed MYL-1401H Solution for Subcutaneous Injection that is the subject of its BLA No. 761075, would not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '997 patent asserted under 35 U.S.C. § 271(g).

**SEVENTH DEFENSE**

7. The claims of the '997 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or judicially created doctrines of invalidity, including double-patenting.

**EIGHTH DEFENSE**

8. To the extent Plaintiffs claim that the manufacture and clinical use of Mylan GmbH's proposed MYL-1401H Solution for Subcutaneous Injection that is the subject of its BLA No. 761075 related to the development and submission of information to the U.S. Food and Drug Administration, is an act of infringement, Defendants are exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e).

**NINTH DEFENSE**

9. The Complaint fails to state a claim for willful infringement and/or exceptional case.

**TENTH DEFENSE**

10. The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(g).

**ELEVENTH DEFENSE**

11. Plaintiffs are not entitled to preliminary or permanent equitable relief.

**TWELFTH DEFENSE**

12. The Court lacks subject matter jurisdiction over any and all claims asserted against Mylan N.V., Mylan Inc. and Mylan Pharmaceuticals Inc.

**THIRTEENTH DEFENSE**

13. Any claim of infringement of the ’997 patent would be limited by the doctrine of prosecution history estoppel.

**FOURTEENTH DEFENSE**

14. Mylan N.V., Mylan Inc. and Mylan Pharmaceuticals Inc. are not proper parties to this action.

**FIFTEENTH DEFENSE**

15. Any additional defenses or counterclaims that discovery may reveal.

## COUNTERCLAIMS

Defendant Mylan GmbH ("Mylan" or "Defendant") hereby counterclaims against Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Amgen" or "Plaintiffs") as follows:

1. Mylan GmbH is a company organized under the laws of Switzerland, having a place of business at Thurgauerstrasse 40, 8050 Zürich, Switzerland.

2. On information and belief, Amgen Inc. purports to be a corporation organized and existing under the laws of Delaware with its corporate headquarters at One Amgen Center Drive, Thousand Oaks, California 91320.

3. On information and belief, Amgen Manufacturing Limited purports to be a corporation organized and existing under the laws of Bermuda, with a place of business at Road 31 Km 24.6, Juncos, Puerto Rico, 00777-4060.

## JURISDICTION AND VENUE

4. Defendant's counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has original subject matter jurisdiction to hear Defendant's counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Plaintiffs because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing the above-captioned action against Defendant in the United States District Court for the Western District of Pennsylvania.

7. Venue with respect to the counterclaims is proper in this district because, *inter alia*, Plaintiffs filed their Complaint in this district.

8. An actual and justiciable controversy has arisen and now exists between the parties because, among other reasons, Plaintiffs have filed the above-captioned action against Defendant alleging infringement of U.S. Patent No. 8,273,707 ("the '707 patent") and U.S. Patent No. 9,643,997 ("the '997 patent"). As explained below, Amgen identified the '707 patent, and U.S. Patent No. 8,940,878 ("the '878 patent"), pursuant to 42 U.S.C. § 262(*l*)(3)(A), and the '997 patent, pursuant to 42 U.S.C. § 262(*l*)(7), which Amgen alleged reasonably could be asserted against Mylan GmbH if it were to manufacture, use, offer for sale, or sell in the United States, or import into the United States the product that is the subject of Mylan GmbH's Biologics License Application ("BLA") No. 761075 ("Mylan GmbH's BLA"). Further, on June 12, 2017, Mylan GmbH provided notice of commercial marketing to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(8)(A).

## BACKGROUND

### NEULASTA® and Plaintiffs' Related Litigations

9. NEULASTA®, Plaintiffs' pegfilgrastim product, was approved by the U.S. Food and Drug Administration ("FDA") on January 31, 2002. Pegfilgrastim and biological products containing pegfilgrastim were disclosed and claimed in Plaintiffs' now-expired U.S. Patent No. 5,824,784 ("the '784 patent"), which was filed in October 1994, issued on October 20, 1998 and expired October 20, 2015. Now, Plaintiffs seek to delay the marketing of Mylan GmbH's Proposed BLA Product and extend its exclusivity well beyond its now-expired '784 patent and the twelve (12) years exclusivity contemplated by the Biologics Price Competition and Innovation Act ("BPCIA").

10. Additionally, methods for purifying granulocyte colony stimulating factor ("GCSF"), which is used to produce pegfilgrastim, were disclosed and claimed by Plaintiffs as

early as 1998, in Plaintiffs' now-expired U.S. Patent No. 5,849,883 ("the '883 patent"), which was filed in May 1996 and issued on December 15, 1998.

11. On August 6, 2015, Plaintiffs filed a complaint alleging infringement of the now-expired '784 patent and U.S. Patent No. 8,952,138 ("the '138 patent") against Apotex related to Apotex's submission of a BLA seeking approval to market a biologic product that is biosimilar to NEULASTA®. On September 6, 2016, the United States District Court for the Southern District of Florida found Apotex does not infringe the asserted claims of the '138 patent. On November 13, 2017, the Federal Circuit affirmed the judgment of the Southern District of Florida.

12. At trial in the United States District Court for the Southern District of Florida, Dr. Roger Hart, a named inventor according to the face of the '138 patent, testified on behalf of Amgen that Amgen does not use the method claimed in the '138 patent for the manufacture of NEULASTA®. Specifically, Dr. Hart testified that "[t]he processes to produce human-grade Neupogen and Neulasta . . . existed, was licensed, was validated, and was providing patients with commercial-grade material at the time of this invention." On information and belief, Plaintiffs do not practice the method claimed in the '138 patent in the manufacture of NEULASTA®.

13. On May 12, 2016, Plaintiffs filed a complaint alleging patent infringement of the now-expired '784 patent and the '878 patent against Sandoz related to Sandoz's submission of a BLA seeking approval to market a biologic product that is biosimilar to NEULASTA®.

14. The '878 patent has a terminal disclaimer over U.S. Patent Application Serial No. 12/820,087, which issued as the '138 patent. The application that issued as the '878 patent was not filed until June 24, 2010, over eight (8) years after Plaintiffs first marketed NEULASTA®.

On information and belief, Plaintiffs do not practice the method claimed in the ’878 patent in the manufacture of NEULASTA®.

15. On May 10, 2017, Plaintiffs filed a complaint alleging patent infringement of the ’707 patent against Coherus related to Coherus’ submission of a BLA seeking approval to market a biologic product that is biosimilar to NEULASTA®.

16. The application that issued as the ’707 patent was not filed until June 23, 2010, over eight (8) years after Plaintiffs first marketed NEULASTA®. On information and belief, Plaintiffs do not practice the method claimed in the ’707 patent in the manufacture of NEULASTA®.

17. The application that issued as the ’997 patent is a divisional of the application that issued as the ’878 patent, and was not filed until January 16, 2015, over twelve (12) years after Plaintiffs first marketed NEULASTA®. On information and belief, Plaintiffs do not practice the method claimed in the ’997 patent in the manufacture of NEULASTA®.

**BPCIA**

18. The BPCIA created a new abbreviated approval pathway for FDA to review and approve biosimilar biologic products, as well as a new mechanism to potentially resolve and address patent disputes that may arise with respect to such products.

19. The BPCIA reflects a careful and critical balance between innovation and price competition. On one side, Congress created an abbreviated licensure pathway that allows applicants to file BLAs under 42 U.S.C. § 262(k) for biological products shown to be biosimilar to, or interchangeable with, a licensed reference product. In exchange, Congress granted reference product sponsors certain periods of exclusivity which prevent applicants from filing a BLA for a biosimilar product for four (4) years from the date the reference product was licensed,

and which delay ultimate eligibility for licensure of a BLA product pursuant to § 262(k) for twelve (12) years from the date the reference product was licensed.

20. A "biosimilar" is a "biologic product that is highly similar to a biologic product that has already been approved by the Food and Drug Administration." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

21. To obtain approval through the BPCIA's abbreviated process, an applicant must show that its biosimilar product is "highly similar" to the "reference product" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2); *see also id.* § 262(k). Specifically, FDA determines if "the biological product is biosimilar to a reference product based upon data derived from" required studies, including:

> a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product.

*Id.* § 262(k)(2)(A)(i).

22. Recognizing that patent disputes between the reference product sponsor and the biosimilar applicant may exist, the "BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Sandoz*, 137 S. Ct. at 1670 (citing 42 U.S.C. § 262(*l*)).

23. Specifically, the BPCIA describes a series of optional steps to exchange information between the parties that begins with the biosimilar applicant providing "a copy of the application submitted . . . and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C.

§ 262(*l*)(2)(A). Optionally, the applicant additionally "may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." *Id.* § 262(*l*)(2)(B).

24. The reference product sponsor must specifically identify "recipients of information" pursuant to § 262(*l*)(1)(B)(ii) with the understanding that such individuals must agree that "confidential access to the information required to be produced" is subject to at least the confidentiality requirements of § 262(*l*).

25. The reference product sponsor must then provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted" if the biosimilar applicant engages "in the making using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A) (referred to herein as the "3(A) List"). The biosimilar applicant then provides to the reference product sponsor:

> a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application.

*Id.* § 262(*l*)(3)(B)(ii)(I) (referred to herein as the "3(B) Statement"). Alternatively, the biosimilar applicant may provide a statement that it does not intend to begin commercial marketing of its biological product before the date that the patents identified on the 3(A) List expire. *Id.* § 262(*l*)(3)(B)(II).

26. The reference product sponsor then:

> shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the

> biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

42 U.S.C. § 262(*l*)(3)(C) (referred to herein as the "3(C) Statement").

27. If following the reference product sponsor's disclosure of its 3(A) List to the biosimilar applicant, the reference product sponsor obtains a newly issued or licensed patent that it believes "a claim of patent infringement could reasonably be asserted by the reference product sponsor" against the biosimilar applicant:

> not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent.

42 U.S.C. § 262(*l*)(7)(B). Thus, the 3(A) List and the remaining scheme set forth for the exchange of information pursuant to § 262(*l*) must be supplemented to include the newly issued or licensed patent. Accordingly, "not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B)." *Id.* § 262(*l*)(7)(B).

28. Following the exchange of information detailed above, the parties must engage in "good faith negotiations to agree on which, if any, patents . . . shall be the subject of an action for patent infringement." 42 U.S.C. § 262(*l*)(4)(A). If the parties cannot reach an agreement, the BPCIA provides a mechanism by which the patents that will be the subject of any litigation are determined by a further exchange. *Id.* § 262(*l*)(5).

29. Regardless of the mechanism employed, no later than thirty (30) days following the parties negotiations, "the reference product sponsor shall bring an action for patent infringement" with respect to each patent either agreed to between the parties or identified on the parties' § 262(*l*)(5) lists. 42 U.S.C. § 262(*l*)(6).

30. If a reference product sponsor fails to bring suit within thirty (30) days following the completion of the parties negotiations pursuant to either § 262(*l*)(4) or § 262(*l*)(5), "a reasonable royalty" shall be the "sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent." 35 U.S.C. § 271(e)(6).

31. The BPCIA also provides that the biosimilar applicant shall provide "notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product" that is the subject of its biosimilar application. 42 U.S.C. § 262(*l*)(8).

32. Once notice is received pursuant to 42 U.S.C. § 262(*l*)(8), there is no limitation under the BPCIA on an applicant's right to bring an action under 28 U.S.C. § 2201 for a declaration of non-infringement, invalidity or unenforceability of any patent included in a reference product sponsor's 3(A) List (including any supplements pursuant to § 262(*l*)(7)). 42 U.S.C. § 262(*l*)(9).

**THE PARTIES' EXCHANGES PURSUANT TO 42 U.S.C. § 262*(l)***

33. On December 9, 2016, Mylan GmbH submitted BLA No. 761075 to FDA pursuant to 42 U.S.C. § 262(k) ("Mylan GmbH's BLA"), seeking approval of MYL-1401H Solution for Subcutaneous Injection, a proposed biosimilar to NEULASTA®. On February 17, 2017, Mylan GmbH notified Amgen that Mylan GmbH's BLA had been accepted for review by FDA and sought to negotiate the terms of access to Mylan GmbH's confidential information, including signed undertakings by all representatives identified by Amgen pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii). Mylan GmbH sought these undertakings, which reflected the express terms of confidential access pursuant to 42 U.S.C. § 262(*l*)(1), to protect its highly confidential and

proprietary information, the unauthorized disclosure of which will cause Mylan GmbH irreparable harm for which there is no adequate legal remedy pursuant to 42 U.S.C. § 262(*l*)(1)(H). Amgen refused to negotiate the terms of access with Mylan GmbH.

34. On March 2, 2017, Mylan GmbH provided Amgen with access to Mylan GmbH's BLA and "other information" as described in § 262(*l*)(2)(A). Specifically, Mylan GmbH provided access to over 175,000 pages of information, which included hundreds of pages of other manufacturing information beyond what was found in Mylan GmbH's BLA, which "describe[] the process or processes used to manufacture the biological product that is the subject of such application."

35. Mylan GmbH provided Amgen confidential access to the information required pursuant to 42 U.S.C. § 262(*l*)(2)(A). Specifically, each representative identified by Amgen, pursuant to 42 U.S.C. § 262(*l*)(1)(B)(ii), was provided confidential access to a searchable, hyperlinked, electronic copy of Mylan GmbH's BLA in its entirety and hundreds of pages of "other" manufacturing information beyond that provided in Mylan GmbH's BLA, also searchable and electronically available.

36. On March 2, 2017, Amgen acknowledged that "Mylan's BLA had been made available." Although Amgen alleged Mylan GmbH failed to provide a "copy" of its BLA, Amgen declined to identify any specific documents or information it was unable to access or view, despite Mylan GmbH's repeated written invitations to do so.

37. In continuing exchanges between Mylan GmbH and Amgen, Mylan GmbH always maintained that it had, in good-faith, fully complied with 42 U.S.C. § 262(*l*)(2)(A), in both the substance and format of its disclosures. On information and belief, Mylan GmbH's March 2, 2017 production of Mylan GmbH's BLA and other manufacturing information

pursuant to 42 U.S.C. § 262(*l*)(2)(A) have remained, and continue to remain, available and accessible in their entirety. To date, Amgen still has not identified any specific documents it was unable to access, review, or search, including any specific pages of Mylan GmbH's BLA and other disclosures.

38. Mylan GmbH is not obligated to provide print and save privileges to Amgen under 42 U.S.C. § 262(*l*). Furthermore, the BPCIA states that the confidential information disclosed under § 262(*l*) "is, and shall remain, the property of the subsection (k) applicant" and that there is no "interest in or license to use the confidential information." 42 U.S.C. § 262(*l*)(1)(E).

39. The BPCIA does not dictate the format a § 262(k) applicant must provide a copy of its application, let alone require an applicant to provide its BLA in the same format as provided to FDA. While Mylan GmbH did not provide Amgen a paper copy of BLA No. 761075, Mylan GmbH provided its BLA to Amgen in a format that among other attributes, was (1) fully searchable across the entire text of its BLA, (2) maintained all hyperlinks both within each document and as linked to any other documents in the BLA, (3) maintained the folder and sub folder structure and modules as submitted to FDA, with each module placed in the appropriate folder, (4) followed FDA's eCTD technical specification Table of Contents Headings and Hierarchy, which maintains the hyperlinked TOC navigation in BLA applications, and (5) maintained all the folder naming conventions so that materials are conventionally named as provided to FDA, among other things. In fact, the BPCIA specifically contemplates that rather than provide a paper copy of highly confidential information, an applicant may provide a reference product sponsor "access" to such confidential information. *See* 42 U.S.C. § 262(*l*)(1) (referring to "confidential access to subsection (k) application").

40. On April 24, 2017, fifty-three (53) days into Amgen's sixty (60) day statutory period under 42 U.S.C. § 262(*l*)(3)(A), Mylan GmbH received correspondence from Amgen alleging that Mylan GmbH had only produced its BLA to Amgen and requesting the production of other manufacturing information under 42 U.S.C. § 262(*l*)(2)(A), completely ignoring Mylan GmbH's voluminous March 2, 2017 production to Amgen. Mylan GmbH promptly responded on April 26, 2017, pointing out that it had in fact disclosed other manufacturing information to Amgen pursuant to 42 U.S.C. § 262(*l*)(2)(A)—specifically hundreds of pages of "other information" pursuant to § 262(*l*)(2)(A) that addressed, among other things, downstream process steps associated with the production of Mylan GmbH's Proposed BLA Product. Amgen later admitted that Mylan GmbH had in fact produced other manufacturing information to Amgen during the parties May 16, 2017 teleconference.

41. Mylan GmbH maintained that it had complied with its statutory obligation to produce "other information" pursuant to 42 U.S.C. § 262(*l*)(2)(A), but remained willing to reasonably consider any specific requests for additional non-cumulative information. During a May 16, 2017 teleconference between the parties, Amgen acknowledged that Mylan GmbH's March 2, 2017 production included "other information" regarding manufacturing pursuant to § 262(*l*)(2)(A) outside Mylan GmbH's BLA, including documents that addressed manufacturing steps and categories of information identified in Amgen's April 24, 2017 correspondence. Amgen clarified that its request was for "additional information," pursuant to § 262(*l*)(2)(B), of certain categories of documents regarding manufacturing, additional to those already produced by Mylan GmbH, that it contended may exist. Although any such production by Mylan GmbH would be optional pursuant to § 262(*l*)(2)(B), Mylan GmbH agreed to consider Amgen's request

for "additional information" to the extent such documents may exist and would be non-cumulative of information Mylan GmbH had already produced.

42. On May 1, 2017, the last day of Amgen's sixty (60) day period pursuant to 42 U.S.C. § 262(*l*)(3)(A), Amgen identified two (2) patents, the '878 patent and the '707 patent, on its 3(A) List.

43. On June 5, 2017, well within Mylan GmbH's sixty (60) day period, pursuant to 42 U.S.C. § 262(*l*)(3)(B), Mylan GmbH provided a detailed 3(B) Statement for each of the '878 patent and the '707 patent, which described on a claim-by-claim basis the factual and legal bases of Mylan GmbH's opinion that the '878 patent and the '707 patent, respectively, are invalid, unenforceable, and/or will not be infringed by Mylan GmbH's Proposed BLA Product. Specifically, Mylan GmbH provided a 103-page detailed 3(B) Statement with respect to the '878 patent with detailed descriptions of Mylan GmbH's non-infringement and invalidity positions, including pinpoint citations to Mylan GmbH's BLA and descriptions of the prior art. For each defense (i.e., no literal infringement, no infringement under the doctrine of equivalents, anticipation and obviousness or invalid for obviousness-type double patenting), Mylan GmbH's 3(B) Statement provided a separate statement with pinpoint citations to relevant support for each of the twenty-five (25) claims of the '878 patent. Similarly, Mylan GmbH provided an 86-page detailed 3(B) Statement with respect to the '707 patent with detailed descriptions of Mylan GmbH's non-infringement and invalidity positions, including pinpoint citations to Mylan GmbH's BLA and descriptions of the prior art. And again, for each defense (i.e., no literal infringement, no infringement under the doctrine of equivalents, anticipation and obviousness or invalid for obviousness-type double patenting), Mylan GmbH's 3(B) Statement provided a

separate statement with pinpoint citations to relevant support for each of the thirteen (13) claims of the ’707 patent.

44. In a letter dated June 7, 2017, Amgen stated that “[p]ursuant to 42 U.S.C. § 262(*l*)(7), Amgen hereby supplements the list that Amgen provided to Mylan under 42 U.S.C. § 262(*l*)(3)(A)” to include the ’997 patent. Two (2) days later on June 9, 2017, and well within the thirty (30) day period available pursuant to 42 U.S.C. § 262(*l*)(7)(B), Mylan GmbH provided a 112-page detailed 3B Statement describing on a claim-by-claim basis the factual and legal bases of Mylan GmbH’s opinion that the ’997 patent is invalid, unenforceable, or will not be infringed by Mylan GmbH’s Proposed BLA Product. Mylan GmbH’s 112-page detailed Statement, pursuant to 42 U.S.C. § 262(*l*)(7), provided detailed non-infringement and invalidity positions, including pinpoint citations to Mylan GmbH’s BLA and descriptions of the prior art. For each defense (i.e., no literal infringement, no infringement under the doctrine of equivalents, anticipation and obviousness or invalid for obviousness-type double patenting), Mylan GmbH’s Statement provided a separate statement with pinpoint citations to relevant support for each of the thirty (30) claims of the ’997 patent.

45. Pursuant to 42 U.S.C. § 262(*l*)(8)(A), on June 12, 2017, Mylan provided its Notice of Commercial Marketing to Amgen.

46. On August 4, 2017, the last day of Amgen’s sixty (60) day period to provide a response pursuant to 42 U.S.C. § 262(*l*)(3)(C), Amgen purportedly provided its 3(C) Statements with respect to the ’707 and ’878 patents to Mylan GmbH. Amgen’s 3(C) Statements failed to provide a “detailed” statement “on a claim by claim basis” with respect to the factual and legal basis for Amgen’s infringement contentions and failed to respond to Mylan GmbH’s detailed invalidity contentions set forth in its June 5, 2017 3(B) Statements, in some cases entirely failing

to address invalidity contentions set forth by Mylan GmbH. Amgen addressed claims in blocks, not on a claim by claim basis, and omitted responses to select claims of each patent. As one example, Amgen summarily addressed anticipation of claims 7, 8, 11 and 13-17 of the '878 patent failing to provide validity positions responsive to Mylan GmbH's assertions for ***each*** claim of the '878 patent. Additionally, despite Mylan GmbH's statement addressing the obviousness of each of the twenty-five (25) claims of the '878 patent on a claim by claim basis, Amgen's statement contained only a one-paragraph response that purported to address all the claims of the '878 patent.

47. Following correspondence from Mylan GmbH stating that Amgen failed to provide a responsive 3(C) Statement with respect to the '997 patent, on August 8, 2017, Amgen provided a 2-page letter that it alleged was its 3(C) Statement regarding the '997 patent. Therein, Amgen simply stated that:

> the '997 Patent is valid and will be infringed by the commercial marketing of Mylan's Proposed Pegfilgrastim Product for essentially the same factual and legal bases as described for the '878 Patent in Amgen's statement under 42 U.S.C. § 262(*l*)(3)(C) served on Mylan on August 4, 2017.

Amgen's three-paragraph 3(C) Statement failed to provide a "detailed" statement "on a claim by claim basis" with respect to the factual and legal basis for Amgen's infringement contentions and entirely failed to address Mylan GmbH's non-infringement and invalidity contentions specific to the '997 as set forth in its June 9, 2017 3(B) Statement. To date, Amgen has failed to provide Mylan GmbH with any detailed explanation of the factual and legal basis of Amgen's claim that the '997 patent claims are allegedly infringed by Mylan GmbH's Proposed BLA Product or address Mylan GmbH's separate and distinct validity and non-infringement positions with respect to the '997 patent.

48. On August 7, 2017, Mylan GmbH consented to immediate patent litigation on the '878 patent, the '707 patent, and the '997 patent pursuant to 42 U.S.C. § 262(*l*)(6).

49. Between August 9, 2017 and August 24, 2017, Mylan GmbH and Amgen engaged in negotiations pursuant to 42 U.S.C. § 262(*l*)(4), but failed to agree on a final and complete list of which, if any, patents on Amgen's 3(A) List would be the subject of an action for patent infringement pursuant to § 262(*l*)(6). Amgen agreed that the '707 and '997 patents should be included, but that at that time, Amgen did not intend to pursue suit on the '878 patent. Mylan GmbH proposed that all three (3) patents on Amgen's 3(A) List be the subject of an immediate suit—the '878, '997 and '707 patents.

50. Unable to reach agreement, on August 25, 2017, Mylan GmbH and Amgen engaged in a simultaneous exchange of patent lists pursuant to 42 U.S.C. § 262(*l*)(5)(B), in which Mylan GmbH identified three (3) patents on its list—the '878, '997 and '707 patents.

51. On September 22, 2017, Amgen filed the present action alleging infringement of the '707 patent and the '997 patent. Amgen did not file suit with respect to the '878 patent—which was listed on Mylan GmbH's patent list pursuant to 42 U.S.C. § 262(*l*)(5)(B)—and thus the sole and exclusive remedy that Amgen may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of Mylan GmbH's Proposed BLA Product infringes the '878 patent is a reasonable royalty pursuant to 35 U.S.C. § 271(e)(6).

## PATENTS-IN-SUIT

### The '707 patent

52. On or about September 25, 2012, the U.S. Patent and Trademark Office ("PTO") issued the '707 patent, titled "PROCESS FOR PURIFYING PROTEINS" to Anna Senczuk and Ralph Klinke.

53. Amgen purports and claims to own, and have the right to enforce, the ’707 patent.

**The ’997 patent**

54. On or about May 9, 2017, the PTO issued the ’997 patent, titled “CAPTURE PURIFICATION PROCESSES FOR PROTEINS EXPRESSED IN A NON-MAMMALIAN SYSTEM” to Joseph Edward Shultz and Roger Hart.

55. The ’997 patent issued from U.S. Patent Application Serial No. 14,599/336 (“the ’336 application”), filed on January 16, 2015, as a divisional of U.S. Patent Application Serial No. 12/822,990 (“the ’990 application”), which was filed on June 24, 2010 and issued as the ’878 patent.

***The ’990 Application***

56. As filed, claim 9 of the ’990 application purported to claim the following:

> A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
> (a) expressing a protein in a non-native limited solubility form in a non-mammalian cell;
> (b) lysing a non-mammalian cell;
> (c) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
> (i) a denaturant;
> (ii) a reductant; and
> (iii) a surfactant;
> (d) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:
> (i) a denaturant;
> (ii) an aggregation suppressor;
> (iii) a protein stabilizer; and
> (iv) a redox component;
> (e) applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;
> (f) washing the separation matrix; and
> (g) eluting the protein from the separation matrix.

57. In an August 28, 2012 Office Action, the Examiner rejected pending claims 1-29 of the '990 application. Therein, the Examiner stated that claim 9 of the '990 application was rejected, among other reasons, under 35 U.S.C. § 102(b) as being anticipated by Oliner et al. (U.S. Patent No. 7,138,370 ("the '370 patent")) which disclosed:

> a method of producing Fc-fusion proteins by expressing them in *E. coli* cells, lysing the cells (which contain the proteins in inclusion bodies), solubilizing the proteins with a solution containing guanidine and DTT, followed by forming a refolding solution by diluting the solubilization solution into a solution containing urea, arginine and cysteine (an alternate solution also contained glycerol and cystamine), which was then filtered and loaded onto an ion exchange chromatography column, followed by elution to remove the protein.

58. On January 25, 2013, Amgen submitted an amendment to claim 9 of the '990 application to read as follows:

> A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
> (a) expressing a protein in a non-native limited solubility form in a non-mammalian cell:
> (b) lysing a non-mammalian cell;
> (c) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
> (iv) a denaturant;
> (v) a reductant; and
> (vi) a surfactant;
> (d) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:
> (v) a denaturant;
> (vi) an aggregation suppressor;
> (vii) a protein stabilizer; and
> (viii) a redox component;
> (e) applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;
> (f) washing the separation matrix;
> (g) eluting the protein from the separation matrix, wherein the separation matrix <u>is a non-affinity resin selected from the</u>

> group consisting of ion exchange, mixed mode, and a hydrophobic interaction resin.

59. In a January 25, 2013 Amendment, Amgen attempted to traverse the Examiner's August 28, 2012 rejection. Specifically, Amgen argued that:

> [t]he claimed invention at step (e) indicates that the refold solution is applied to a separation matrix. In contrast, the patent of Oliner et al. teaches . . . that the refolded protein is subject to dialysis, precipitation, and centrifugation. The supernatant is then pH adjusted and loaded onto a column. Thus, Oliner et al. teaches a method that differs markedly from the direct application of refold solution to the separation matrix.

60. On September 9, 2013, the Examiner issued a Final Office Action rejecting claim 9 of the '990 application. Specifically, the Examiner stated:

> Applicant asserts . . . that Oliner teaches a method that differs markedly from the direct application of refold solution to the separation matrix. Applicant's arguments have been fully considered and are not persuasive for the following reasons: The claims are not limited to a method requiring direct application of refold solution to the separation matrix. The claim clearly states that the method *comprises* the listed steps. Therefore, additional steps may be added. There is nothing in the claim which precludes additional purification steps.

61. On January 9, 2014, Amgen submitted an amendment to claim 9 of the '990 application to read as follows:

> A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
> (a) expressing a protein in a non-native limited solubility form in a non-mammalian cell;
> (b) lysing a non-mammalian cell;
> (c) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
> (i) a denaturant;
> (ii) a reductant; and
> (iii) a surfactant;
> (d) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:

(iv) a denaturant;
(v) an aggregation suppressor;
(vi) a protein stabilizer; and
(vii) a redox component;

(e) directly applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;

(f) washing the separation matrix; and

(g) eluting the protein from the separation matrix, wherein the separation matrix is a non-affinity resin selected from the group consisting of ion exchange, mixed mode, and a hydrophobic interaction resin.

Amgen also argued that claim 9 as amended was consistent with the specification, which claims "the refolded protein of interested [sic] is applied directly to the separation matrix, without the need for diluting or removing the components of the solution required for refolding the protein." Amgen thus requested withdrawal of the Examiner's rejection of claim 9 of the '990 application based upon its amendment.

62. In a June 6, 2014 Office Action, the Examiner withdrew its rejection of claim 9 of the '990 application in light of Amgen's amendment and argument.

***The '336 Application***

63. In an October 2, 2015 Office Action, the Examiner rejected pending claims 1-20 of the '336 application. Therein, the Examiner stated that claim 9 of the '336 application was rejected, among others, under 35 U.S.C. § 102(b) as being anticipated by the '370 patent, which disclosed:

> a method of producing Fc-fusion proteins by expressing them in *E. coli* cells, lysing the cells (which contain the proteins in inclusion bodies), solubilizing the proteins with a solution containing guanidine and DTT, followed by forming a refolding solution by diluting the solubilization solution into a solution containing urea, arginine and cysteine (an alternate solution also contained glycerol and cystamine), which was then filtered and loaded onto an ion exchange chromatography column, followed by elution to remove the protein.

64. On March 1, 2016, Amgen submitted an amendment to claim 9 of the '336 application to read as follows:

> A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
> ~~(a) expressing a protein in a non-native limited solubility form in a non-mammalian cell;~~
> ~~(b) lysing a non-mammalian cell;~~
> (a) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
> (i) a denaturant;
> (ii) a reductant; and
> (iii) a surfactant;
> (b) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:
> (iv) a denaturant;
> (v) an aggregation suppressor;
> (vi) a protein stabilizer; and
> (vii) a redox component;
> (c) applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;
> (d) washing the separation matrix; and
> (e) eluting the protein from the separation matrix.

65. In a March 1, 2016 Response to October 2, 2015 Non-Final Office Action, Amgen attempted to traverse the Examiner's rejection. Specifically, Amgen argued that:

> the '370 patent recites that the refolded protein is subject to dialysis, precipitation, and centrifugation. The supernatant of the '370 patent is then pH adjusted and loaded onto a column. Because the '370 patent does not recite forming a refold solution and applying the refold solution to a separation matrix, the '370 patent fails to teach each and every element of claim 1.

66. Amgen's argument in its March 1, 2016 Response in the '336 application regarding the '370 patent is the same argument Amgen made in its January 25, 2013 Response of the parent '990 application. Specifically, in both instances, Amgen argues that the '370 patent

contains intervening purification steps (i.e., dialysis, precipitation and centrifugation) before applying the refold solution to a separation matrix.

67. Conversely, both claim 9 of the '990 application as amended in the January 25, 2013 Amendment and claim 9 of the '336 application as amended in the March 1, 2016 Amendment require direct application of the refold solution to the separation matrix.

68. At the time of Amgen's January 25, 2013 Amendment in the '990 application, limitation (e) of claim 9 was identical to limitation (c) of claim 9 of the '997 patent.

69. In an August 4, 2016 Order Construing Claims issued by the United States District Court for the Northern District of California in *Amgen Inc. et al. v. Sandoz Inc. et al*., Civil Action No. 14-cv-04741-RS, the Court found:

> [Amgen's] attempt to distinguish the claimed method from the prior art, and the '370 Patent, in particular, clarify that [Amgen] believed there should not be any intermediary steps between the refolding process and application of such solution to the separation matrix.

70. In an August 4, 2016 Order Construing Claims issued by the Northern District of California in *Amgen Inc. et al. v. Sandoz Inc. et al*., Civil Action No. 14-cv-04741-RS, certain terms of the '878 patent, including terms that are also present in the '997 patent, were construed as follows:

- the phrase "directly applying the refold solution to a separation matrix" was construed as "[a]pplying the refold solution to a separation matrix without removing components of or diluting the refold solution[;]"
- the phrase "under conditions suitable for the protein to associate with the matrix" was construed as "[u]nder conditions suitable for the protein to be purified to bind to the matrix[;]"

- the phrase "eluting the protein from the separation matrix" was construed as "[a]pplying a solution that reverses the binding of the purified protein to the separation matrix[;]" and,
- the phrase "washing the separation matrix" was construed as "adding a solution to the separation matrix to remove materials in the refold solution while preserving binding of the protein to be purified."

71. Claim 9 of the '336 application issued as claim 9 of the '997 patent.

72. Amgen purports and claims to own, and have the right to enforce, the '997 patent.

**COUNT I**
**(Declaratory Judgment of Non-Infringement of the '707 Patent)**

73. Defendant re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

74. There is an actual, substantial and continuing justiciable case or controversy between Defendant and Amgen regarding non-infringement of the '707 patent.

75. The manufacture, use, sale, offer for sale or importation of Mylan GmbH's Proposed BLA Product that is the subject of Mylan GmbH's BLA No. 761075 have not infringed, do not infringe, and would not, if marketed, infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '707 patent.

76. Defendant is entitled to a judicial declaration that the manufacture use, sale, offer for sale or importation of Mylan GmbH's Proposed BLA Product that is the subject of Mylan GmbH's BLA No. 761075 have not infringed, do not infringe, and would not, if marketed, infringe, any valid and/or enforceable claim of the '707 patent.

**COUNT II**
**(Declaratory Judgment of Invalidity of the '707 Patent)**

77. Defendant re-asserts and re-alleges each of the foregoing Paragraph as if fully set forth herein.

78. There is an actual, substantial and continuing justiciable case or controversy between Defendant and Amgen regarding the invalidity of the '707 patent.

79. One or more of the claims of the '707 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 102, 103, and/or 112, and/or judicially created doctrines of invalidity.

80. Defendant is entitled to a judicial declaration that the claims of the '707 patent are invalid.

**COUNT III**
**(Declaratory Judgment of Non-Infringement of the '997 Patent)**

81. Defendant re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

82. There is an actual, substantial and continuing justiciable case or controversy between Defendant and Amgen regarding non-infringement of the '997 patent.

83. The manufacture, use, sale, offer for sale or importation of Mylan GmbH's Proposed BLA Product that is the subject of Mylan GmbH's BLA No. 761075 have not infringed, do not infringe, and would not, if marketed, infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '997 patent.

84. Defendant is entitled to a judicial declaration that the manufacture use, sale, offer for sale or importation of Mylan GmbH's Proposed BLA Product that is the subject of Mylan

GmbH's BLA No. 761075 have not infringed, do not infringe, and would not, if marketed, infringe, any valid and/or enforceable claim of the '997 patent.

**COUNT IV**
**(Declaratory Judgment of Invalidity of the '997 Patent)**

85. Defendant re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

86. There is an actual, substantial and continuing justiciable case or controversy between Defendant and Amgen regarding the invalidity of the '997 patent.

87. One or more of the claims of the '997 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 102, 103, and/or 112, and/or judicially created doctrines of invalidity.

88. Defendant is entitled to a judicial declaration that the claims of the '997 patent are invalid.

**DEMAND FOR A JURY TRIAL**

Defendant hereby demands a jury trial on all issues so triable.

**PRAYER FOR RELIEF**

WHEREFORE, Defendant respectfully requests that the Court enter a judgment in its favor and against Amgen:

A. Declaring that manufacture, use, sale, offer for sale or importation of Mylan GmbH's Proposed BLA Product that is the subject of Mylan GmbH's BLA No. 761075 have not infringed, do not infringe, and would not, if marketed, infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '707 patent;

B. Declaring that the claims of the '707 patent are invalid;

C. Declaring that manufacture, use, sale, offer for sale or importation of Mylan GmbH's Proposed BLA Product that is the subject of Mylan GmbH's BLA No. 761075 have not infringed, do not infringe, and would not, if marketed, infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '997 patent;

D. Declaring that the claims of the '997 patent are invalid;

E. Ordering that Amgen's Complaint be dismissed with prejudice and judgment entered in favor of Defendant;

F. Declaring this case exceptional and that Defendant is entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285;

G. Awarding Defendant costs and expenses;

H. Awarding Defendant such other and further relief as the Court deems just and proper.

Dated: November 22, 2017

Respectfully submitted,

**PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP**

Counsel for Defendants Mylan Pharmaceuticals Inc., Mylan N.V. and Mylan Inc. and Defendant/Counterclaim-Plaintiff Mylan GmbH

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 22nd day of November, 2017, I electronically filed the foregoing **DEFENDANTS MYLAN INC.'S, MYLAN PHARMACEUTICALS INC.'S, MYLAN GMBH'S AND MYLAN N.V.'S ANSWER, DEFENSES AND COUNTERCLAIMS** with the Clerk of the Court using the CM/ECF system which sent notification to all counsel of record, including the following:

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*/s/ Eric G. Soller*